## The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network Final Report of the Activities of Year One

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October 1995

#### BACKGROUND

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) provide authority to conduct studies related to the quality of clinical laboratory testing and to identify factors that may influence the accuracy and reliability of test results. Since the passage of CLIA, few formal studies have been conducted to obtain information regarding the influence of laboratory regulations on the practice of laboratory medicine.

Data to assess the quality of laboratory testing have largely been gathered from on-site inspection findings and proficiency testing performance. While these give an indication of testing quality, they provide little information regarding the extent and nature of problems in the diagnosis and treatment of patients caused by errors in laboratory testing.

Physician's groups press for a more lenient approach in the enforcement of the CLIA regulations for physician office laboratories (POLs). Their ideas range from new test complexity categorizations to outright exemption of most testing in the POL setting. At the same time, laboratory professionals and consumer groups have organized to preserve high personnel standards and maintain the concept of site neutrality for the regulation of testing. With little data available to determine the effectiveness of the regulations on the quality of laboratory testing, particularly on patient outcomes, these interest groups have a limited ability to defend their positions.

To address these issues, the Washington State Office of Laboratory Quality Assurance (LQA) and the Centers for Disease Control and Prevention (CDC) entered into a cooperative agreement to develop a data collection network in the Pacific Northwest that will provide ongoing information about the practice of laboratory medicine in hospital, physician office and independent laboratories. Data provided by these collaborative laboratories will: document changes in the practice of laboratory medicine; monitor the impact of CLIA; provide information about changes required in the implementation of CLIA as the practice of laboratory medicine expands into preventive services under health care reform; and address other public health needs.

Data gathered through this cooperative agreement will ultimately improve patient care by improving the quality of clinical laboratory medicine.

## CREATING THE LABORATORY MEDICINE SENTINEL MONITORING NETWORK

In September 1994, the Washington State Office of Laboratory Quality Assurance was in an excellent position to rapidly develop a network of laboratories for this project. Having implemented its own set of laboratory regulations in 1990, and obtained a state exemption from CLIA in 1993, Washington had developed a strong working relationship with the laboratory community in the state.

#### Laboratory selection

At the time of selection of laboratories for the network, there were 945 laboratories listed in the Washington State Medical Test Site (MTS) database as performing moderate or high complexity testing. An estimate of the necessary sample size was made using the Sample Size and Power calculation available in the CDC's *Epi-Info 5.0* data package. To assure statistical significance at the 99% confidence level (using an expected frequency of 30% and a worst acceptable frequency of 50%) a minimum of 26 independent laboratories, 27 hospital laboratories and 32 POLs would need to be selected. These estimates were rounded up to give the following minimum numbers of participant laboratories for the network: 30 independent; 30 hospital; and 40 physician office laboratories.

As a means to assure adequate participation, the Office of Laboratory Quality Assurance obtained the support of other states in the Health Care Financing Administration (HCFA) Region X: Alaska, Idaho, Oregon. Each state agreed to supply the Network Director a listing of laboratories in their state. By incorporating laboratories from these other states into the network, the data would then include laboratories regulated under the CLIA program (Alaska, Idaho, Oregon) and those under a CLIA-exempt program (Washington). In addition, there would be a sampling of data from states which had initiated health care reform measures (Oregon and Washington), and those which had not (Alaska and Idaho).

In January 1995, two forms of solicitation were used to enroll laboratories into the network. A mass mailing went out to nearly 1040 laboratories in the Pacific Northwest region. Laboratory directors in all licensed laboratories performing moderate or high complexity testing in the state of Washington, and 90 randomly selected laboratories in Alaska, Idaho and Oregon received a letter soliciting their voluntary participation. Laboratories agreeing to participate were asked to return an "Agreement to Participate" form which was enclosed in the packet of information.

The advantage to this type of solicitation was that all laboratories had an equal chance to participate on a truly voluntary, unpressured basis. There would be no selection bias by the LQA staff due to their exposure to a particular laboratory from regulatory oversight activities or other positive or negative interactions.

In this solicitation letter, laboratories were assured that the results of their input on data gathering devices would remain confidential and that study findings would be shared with all participants. As a further incentive, tuition coupons for public health courses held throughout the state were promised to the first 100 laboratories agreeing to participate in the network.

As a second approach, a focused phone solicitation was planned to further encourage participation, in the event that sufficient numbers of laboratories were not enrolled from the mass mailing approach. One hundred forty laboratories (40 hospital, 40 independent and 60 physician office laboratories) were selected at random by the Network Director to be called by the project staff in their geographical region. Phone calls would begin two weeks after the mass mail out of the solicitation letter. Due to an excellent response to the solicitation letter, very few phone calls

were necessary to meet the minimum goals set for each type of laboratory.

#### Laboratories That Agreed to Participate

A total of 266 laboratories agreed to participate in the network. Two hundred forty one were from Washington, 6 from Alaska, 8 from Idaho and 11 from Oregon.

Prior to the assignment of confidential code numbers to the participant laboratories and the release of the first questionnaire, demographic information was extracted from the MTS and CLIA databases. This information pertained to laboratory type (hospital, independent, POL); annual test volumes; accreditation status and test specialties. Urban and rural designations were determined using a United States Census Bureau database to categorize laboratories by zipcode.

## **RELEASE OF QUESTIONNAIRE 1**

The first questionnaire was released to all network participant laboratories in June 1995. Laboratories responded to questions that solicited general laboratory information (accreditation status, laboratory specialties, testing complexity and personnel) and assessed various quality assurance monitors in use. A two week turnaround time was given for the return of the completed questionnaire.

After four weeks from the release of the questionnaire, laboratories that had not returned a questionnaire were called to encourage the completion and return of the form. With these efforts, 229 laboratories returned completed questionnaires in time for data analysis, an 86% response rate.

## Laboratory types

Of the 229 laboratories that responded to questionnaire one, 133 laboratories (58%) were physician office laboratories, 56 (24%) were hospital laboratories and 40 (18%) were independent laboratories.

Laboratories that were categorized as physician office laboratories were comprised of the following subtypes: POLs; clinics; community health clinics; health departments or health districts; student health centers; health maintenance organizations; rural health clinics and other. (Tables 1 and 2).

## Urban/Rural Designations

One hundred sixty four laboratories (72%) were designated urban, central county of a metropolitan statistical area (MSA); 2 (1%) were designated urban, not the central county of a MSA; and 63 (27%) were designated rural.

## Annual Test Volumes

In the state of Washington, laboratories are instructed to count each test in a panel or profile as a separate test, with the exception of complete blood counts, which they count as a single test.

According to CLIA, laboratories are to count each test in a panel or profile as a separate test, including those in a complete blood count. Table 3 shows the distribution of laboratories according to estimated annual test volumes.

#### Laboratory Specialties

Data regarding the specialties performed by each participant laboratory were extracted from the MTS or CLIA databases. This information was compared with each laboratory's response to a question regarding specialties and test complexity. (Microscopic procedures were excluded from this comparison however, since Washington state and CLIA address the categorization for this testing differently for licensing purposes). While confirming proficiency testing enrollment and verifying information on licensure application forms, the LQA staff had recognized that the concepts of testing specialties and complexity were not well understood by many laboratories. By posing a question where the laboratories would indicate their test specialties and the level of testing complexity for those specialties, the extent and nature of the misunderstandings could be determined. Table 4 summarizes the specialities performed by laboratories responding to questionnaire one, based on the data extracted from MTS and CLIA databases.

#### Do Laboratories Understand Specialties and Test Complexity?

Ninety seven of the 229 laboratories (42%) did not check specialties that matched what had been determined from the MTS or CLIA databases for moderate or high complexity testing. When looking at different types of laboratories, the responses of 54 % of the POLs did not match what was on file, with 27% of hospital and 25 % of independent laboratories not matching.

The most misunderstood categories were Microbiology and Diagnostic Immunology, followed by Chemistry, Hematology and Immunohematology. Many laboratories underestimated their test complexity levels, indicating that they performed waived or PPM (Provider Performed Microscopy) tests when we had determined that they perform moderate or high complexity tests for a particular specialty. For Pathology, Histocompatibility and Clinical Cytogenetics, laboratories overestimated their specialties, recording that they did moderate or high complexity testing when we did not list them as performing any testing in these specialties. Although these laboratories may have added or dropped testing since April 1995 to create some of these discrepancies, in most cases proficiency testing data or on-site inspection data supported what had been extracted from the MTS or CLIA databases. (Table 5).

Knowing specialties and test complexity may not affect testing quality or patient outcomes, but an understanding of these allows a laboratory to work effectively within the system. These findings demonstrate that information supplied by facilities about their laboratory testing may be of questionable value unless verified by some other means such as on-site surveys or proficiency testing monitoring. These also explain the basis for the continued problems that the Office of Laboratory Quality Assurance has had with testing sites properly enrolling in proficiency testing and accurately completing licensure applications and other forms. In the future, laboratories may experience problems receiving reimbursement for testing if they are not recognized as performing testing in a certain specialty.

#### Accreditation Status

Of the 229 laboratories that returned questionnaires, 59 (26%) were found to be accredited by a private organization. The majority of these laboratories were accredited by the College of American Pathologists (CAP) (61%) or by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (39%). The Commission on Office Laboratory Accreditation (COLA) was the accrediting body for 11% of laboratories, with the American Association of Blood Banks (AABB) accrediting 8% and the American Association of Histocompatibility and Immunogenetics (ASHI) accrediting 3%. The American Osteopathy Association was not listed as an accrediting body by any of the laboratories. Nine laboratories are accredited by both the CAP and JCAHO.

Since information had been extracted from the MTS and CLIA databases regarding accreditation status, this was compared with the participant laboratories' responses. Very few laboratories gave incorrect information on their questionnaires regarding their accreditation status. Any incorrect information given was generally obvious in nature. For example, a laboratory would indicate that they were accredited but would list a proficiency testing agency as their accrediting body. When discrepancies were found between the laboratory's response on the questionnaire and the MTS or CLIA database information, we recorded the MTS or CLIA data as the most reliable response. Since accredited laboratories in Washington must submit documentation of their accreditation status at the time of relicensing, this information was verifiable and considered to be the most accurate data.

#### Personnel

The total number of testing personnel per laboratory ranged from one to 852, with (55%) employing less than five testing personnel and 86% employing 20 or less. Laboratory directors were primarily Medical Doctors (57%) or Pathologists (32%). (Table 6)

There were 167 laboratories (73%) which employed at least one person with formal laboratory training (a Medical Technologist or Medical Laboratory Technician). Seventy three laboratories (32%) indicated that they routinely use an outside laboratory consultant.

## QUALITY ASSURANCE MONITORS IN USE

From a list of 15 quality assurance monitors, laboratories were asked to indicate which they formally used. The numbers of laboratories that answered these questions as intended ranged from 204 to 207, depending on the quality assurance monitor assessed.

The average number of monitors in use was 8. Seven laboratories indicated that they used all 15 monitors listed and two laboratories indicated that they used only one of the monitors.

Regardless of laboratory type, the four most frequently used monitors were: *Proficiency Testing Results; Quality Control Results; Documentation of Personnel Competency; and Staff Meetings Where Lab Issues are Discussed.* Each of these monitors were used by at least 75% of all

laboratories in the network.

Quality assurance monitors that were formally used by 50% to 75% of all laboratories were: *Specimen Acceptability; Review of Final Patient Report for Accuracy and Clinical Content; Incident Reports Related to Lab Error; Correlation Studies with Other Labs; and Ordering Accuracy.* A higher percentage of independent laboratories used *Specimen Acceptability* (79%) and *Correlation Studies With Other Labs* (71%) than did hospital laboratories (56% and 39% respectively). And higher percentage of independent laboratories (76%) and hospital laboratories (78%) used *Incident Reports Related to Lab Error* than physician office laboratories (53%).

The Evaluation of Frequency of Corrected Reports, Patient Satisfaction Assessment, Physician Satisfaction Assessment and Evaluation of Patient History versus Lab Result monitors were used by 25% to 50% of all network laboratories. Evaluation of Frequency of Corrected Reports was used by a higher percentage of hospital laboratories (56%) than physician office laboratories (25%). A higher percentage of hospital laboratories used Patient Satisfaction Assessment (50%) than did independent or physician office laboratories (32% and 29% respectively).

The *Evaluation of Patient Outcome* versus *Lab Result* and the *Evaluation of Frequency of Repeat Analysis* were the least frequently used monitors, each used by less than 25% of all laboratories.

Tables 7 and 8 demonstrate the percentages of laboratories that use each monitor, for all laboratories and by each laboratory type.

## Ranking the Value of Feedback from each Quality Assurance Monitor

Laboratories were asked to rank the value of feedback obtained from each quality assurance monitor that they indicated that they used, on a scale of 1 to 5. A ranking of 1 indicated "no value" and a ranking of 5 indicated "very valuable".

For each quality assurance monitor, the percent of laboratories that ranked the value of feedback as valuable or very valuable (4 or 5 respectively) was determined. Using this criteria, *Quality Control Results, Proficiency Testing Results, Correlation Studies with Other Labs, Review of Final Patient Report for Accuracy and Clinical Content, and Staff Meetings Where Lab Issues are Discussed* were ranked as most valuable by the laboratories that used those monitors.

Although the *Documentation of Personnel Competency* was used by a relatively high number of all laboratories (79%), it was perceived to be less valuable than other quality assurance monitors. The assessment of personnel competency is clearly emphasized in the laboratory standards set by regulatory and accrediting agencies and so it is expected that a high percentage of laboratories formally use this monitor. However, only 57% of laboratories ranked this monitor as valuable or very valuable. One comment that appeared on a questionnaire stated that formally documenting personnel competency was "a waste of time" since employees were evaluated on a daily basis by supervisory personnel.

The *Evaluation of Patient Outcome versus Lab Result* was used by only 19% of all laboratories, yet received a relatively high ranking of value (74% of laboratories ranking as a 4 or 5). Physician office laboratories readily have access to this information yet relatively few of the network participant laboratories incorporate this into their laboratory quality assurance program. The correlation of patient outcome to laboratory test results is a difficult and time consuming process, and typically requires a physician or other practitioner to be involved in interpretation of the data. However, the data from these studies are the most sought after and are predicted to be the most definitive in deciding which quality assurance practices, regulatory pressures and market conditions make a difference in optimal patient care.

Table 9 and Figures 1-3 demonstrate how laboratories of all types ranked the value of feedback of each quality assurance monitor. Appendices i - iii show how different laboratory types ranked the value of feedback of each quality assurance monitor.

#### DISCUSSION

The results of this probe on quality assurance monitors will be valuable in several ways. On a short term basis, laboratories may use this data to compare their quality assurance programs to that of the network participant laboratories. By recognizing that a high percentage of laboratories like their own use a certain monitor and that the monitor was generally perceived to be valuable, a laboratory may investigate and adopt a new quality assurance monitor or activity. On a long term basis, the information found on quality assurance monitors in use will be most valuable when analyzing the results of future questionnaires. Data gathered from questions about laboratory-related problems and errors can be related to the presence or absence of certain quality assurance monitors in a particular type of laboratory.

#### **OTHER NETWORK ACTIVITIES**

During the first year of the cooperative agreement, regional meetings were held throughout the state of Washington with the network participants. The purpose of these meetings was to restate the goals of the project, to address any concerns, to gather feedback on the first questionnaire and to solicit input on the content of future questionnaires. By establishing an open dialog and underscoring the benefits of participation, the network laboratory participants were encouraged to make a long term commitment to this project.

Future data gathering devices will probe: Quality Assurance Monitors; the Extent and Nature of Laboratory-Related Problems and Errors; and Access to Laboratory Testing.

#### CONCLUSIONS

Through these monitoring networks, all interested parties will be provided an insight into the

current status of testing quality and the effectiveness of regulations in assuring positive patient outcomes. This information will allow interest groups and regulators to undertake activities based on solid data which reflect actual laboratory practices and experiences. In addition, changes in the practice of laboratory medicine can be assessed as health care reform and other regulatory measures shape the future.

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| Laboratory Type       | Total Labs | Urban |       | Rural |       |
|-----------------------|------------|-------|-------|-------|-------|
| Hospital              | 56         | 29    | (52%) | 27    | (48%) |
| Independent           | 40         | 30    | (75%) | 10    | (25%) |
| Physician Office Labs | 133        | 107   | (80%) | 26    | (20%) |

## TABLE 2 Laboratories Categorized as Physician Office Laboratories

N=133

Number of Lobs

| Laboratory Type                       | Number of Labs |
|---------------------------------------|----------------|
| Physician Office Laboratories         | 90             |
| Clinic                                | 16             |
| Community Health Clinic               | 7              |
| Student Health Center                 | 5              |
| Health Department or District         | 6              |
| Health Maintenance Organization (HMO) | 3              |
| Rural Health Clinic                   | 1              |
| Other                                 | 5              |

# TABLE 3 Laboratory Size Based on Annual Test Volumes

| N=229 |
|-------|
|-------|

| Number of Tests      | Number of Labs |
|----------------------|----------------|
| Less than 2,000      | 46 (20%)       |
| 2,000 to 10,000      | 65 (28%)       |
| 10,001 to 25,000     | 30 (13%)       |
| 25,001 to 50,000     | 19 ( 8%)       |
| 50,001 to 75,000     | 10 (4%)        |
| 75,001 to 100,000    | 5 (2%)         |
| Greater than 100,000 | 54 (24%)       |

|                        | Number of Laboratories that Perform<br>Moderate or High Complexity Testing in the Specialty |                                 |                      |  |
|------------------------|---|---------------------------------|----------------------|--|
| Test Specialty         | Hospital Labs<br>N=56   | <b>Independent Labs</b><br>N=40 | <b>POLS</b><br>N=133 |  |
| Chemistry              | 54 (96%)  | 31 (78%)                        | 84 (63%)             |  |
| Hematology             | 52 (93%)  | 30 (75%)                        | 96 (72%)             |  |
| Microbiology           | 48 (86%)  | 23 (58%)                        | 106 (80%)            |  |
| Diagnostic Immunology  | 48 (86%)  | 31 (78%)                        | 72 (54%)             |  |
| Immunohematology       | 40 (71%)  | 11 (28%)                        | 0                    |  |
| Microscopic Procedures | 44 (79%)  | 19 (48%)                        | 85 (64%)             |  |
| Pathology/Cytology     | 18 (32%)  | 9 (23%)                         | 6 ( 5%)              |  |
| Histocompatibility     | 1 ( 2%)   | 2 ( 5%)                         | 0                    |  |
| Clinical Cytogenetics  | 2 ( 4%)   | 1 ( 3%)                         | 0                    |  |

|  |   | Number of Labs that gave information on the questionnaire that<br>did not match information on file with regulatory agencies<br>(Total Number of Labs responding = 229) |                          |           |            |
|--|---|---|--------------------------|-----------|------------|
| MTS* or CLIA**<br>database information   | Lab's response on questionnaire                                     | Microbiology  | Diagnostic<br>Immunology | Chemistry | Hematology |
| Moderate or high<br>complexity testing done in<br>this specialty                                     | No testing done in this specialty                                   | 34  | 23                       | 12        | 2          |
| Moderate or high<br>complexity testing done in<br>this specialty                                     | Waived or provider<br>performed microscopy<br>testing done          | 9   | 9                        | 6         | 8          |
| No moderate or high<br>complexity testing done in<br>this specialty                                  | Moderate or high<br>complexity testing done<br>in this specialty    | 6   | 8                        | 2         | 3          |
| Moderate or high<br>complexity testing done in<br>this specialty                                     | Testing is done in this<br>speciality but do not<br>know complexity | 3   | 4                        | 2         | 4          |
| Total Number of Labs   | -   | 52  | 44                       | 22        | 17         |
| Number of Labs Classified as POL (%)   |   | 46 (88%)  | 34 (77%)                 | 20 (91%)  | 15 (88%)   |
| Number of Labs Without Formally Trained Testing<br>Personnel (No Medical Technologist or Technician) |   | 30 (58%)  | 15 (34%)                 | 10 (46%)  | 10 (59%)   |

| <b>Comparison of Laboratory</b> | v Responses with Regulatory      | Agency Database Information |
|---------------------------------|----------------------------------|-----------------------------|
| Comparison of Laboratory        | <b>Mesponses</b> with Regulatory | Agency Database mormation   |

|  |  | Immuno-<br>hematology | Pathology/<br>Cytology | Clinical<br>Cytogenetics | Histo-<br>Compatibilty |
|--|--|-----------------------|------------------------|--------------------------|------------------------|
| Moderate or high<br>complexity testing done in<br>this specialty                                     | No testing done in this specialty  | 4                     | 2                      |                          |                        |
| No testing done in this specialty  | Waived or provider<br>performed or moderate<br>or high complexity<br>testing done in this<br>specialty | 11                    | 13                     | 9                        | 9                      |
| Total Number of Labs   |  | 15                    | 15                     | 9                        | 9                      |
| Number of Labs Classified as POL (%)   |  | 9 (60%)               | 10 (67%)               | 7 (78%)                  | 6 (67%)                |
| Number of Labs Without Formally Trained Testing<br>Personnel (No Medical Technologist or Technician) |  | 3 (20%)               | 5 (33%)                | 4 (44%)                  | 3 (33%)                |

\* MTS - Medical Test Site - The laboratory licensure program in the state of Washington.
 \*\* CLIA - Clinical Laboratory Improvement Amendments of 1988 - The federal laboratory licensure program.

## TABLE 6Laboratory Personnel

| Background of Director       | Number of Laboratories |
|------------------------------|------------------------|
| M.D. Staff Physician         | 130 (57%)              |
| M.D. Pathologist             | 74 (32%)               |
| Ph.D.                        | 13 ( 6%)               |
| B.S. Degree                  | 9 ( 4%)                |
| R.N., ARNP, PA or Naturopath | 2 (<1%)                |
| Not given                    | 1 (<1%)                |

| Background of Testing Personnel    | Number of Personnel |
|------------------------------------|---------------------|
| Medical Technologist or Technician | 1433                |
| RN, ARNP, PA or Naturopath         | 957                 |
| M.D.                               | 378                 |
| LPN or Medical Assistant           | 236                 |
| On the Job Trained                 | 185                 |
| Cytotechnologists                  | 39                  |
| Other                              | 118                 |

| Total Number of Testing Personnel | Number of Laboratories |
|-----------------------------------|------------------------|
| 1 to 5                            | 125 (55%)              |
| 6 to 10                           | 39 (17%)               |
| 11 to 20                          | 32 (14%)               |
| 21 to 30                          | 10 (4%)                |
| 31 to 50                          | 9 (4%)                 |
| 51 to 100                         | 11 (5%)                |
| 154                               | 1 (<1%)                |
| 852                               | 1 (<1%)                |
| Not given                         | 1 (<1%)                |

| Quality Assurance Monitor  | Number of<br>Responses | Labs that formally use monitor % |
|--|------------------------|----------------------------------|
| Proficiency Testing Results                                      | 204                    | 98                               |
| Quality Control Results  | 206                    | 91                               |
| Documentation of Personnel Competency                            | 204                    | 79                               |
| Staff Meetings where Lab Issues are Discussed                    | 206                    | 75                               |
| Specimen Acceptability   | 206                    | 67                               |
| Review of Final Patient Report for Accuracy and Clinical Content | 207                    | 64                               |
| Incident Reports Related to Lab Error                            | 207                    | 64                               |
| Correlation Studies with Other Labs                              | 207                    | 56                               |
| Ordering Accuracy  | 207                    | 50                               |
| Evaluation of Frequency of Corrected Reports                     | 207                    | 38                               |
| Patient Satisfaction Assessment                                  | 207                    | 35                               |
| Physician Satisfaction Assessment                                | 207                    | 28                               |
| Evaluation of Patient History vs Lab Result                      | 207                    | 27                               |
| Evaluation of Patient Outcome vs Lab Result                      | 206                    | 19                               |
| Evaluation of Frequency of Repeat Analysis                       | 207                    | 16                               |

 TABLE 7
 Frequency of Use of Quality Assurance Monitors - All Laboratory Types

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# Frequency of Use of Quality Assurance Monitors - By Laboratory Type

|  | Hospital               |                                  | Independent            |                                  | Physician Of           | fice                             |
|--|------------------------|----------------------------------|------------------------|----------------------------------|------------------------|----------------------------------|
| Quality Assurance<br>Monitors                                  | Number of<br>Responses | Labs that<br>use<br>monitor<br>% | Number of<br>Responses | Labs that<br>use<br>monitor<br>% | Number of<br>Responses | Labs that<br>use<br>monitor<br>% |
| Proficiency Testing<br>Results                                 | 54                     | 98                               | 38                     | 97                               | 112                    | 98                               |
| Quality Control<br>Results                                     | 54                     | 94                               | 38                     | 92                               | 114                    | 89                               |
| Incident Reports<br>Related to Lab Errors                      | 54                     | 78                               | 38                     | 76                               | 115                    | 53                               |
| Documentation of<br>Personnel Competency                       | 53                     | 77                               | 38                     | 84                               | 113                    | 79                               |
| Staff Meetings Where<br>Lab Issues are<br>Discussed            | 54                     | 76                               | 38                     | 89                               | 114                    | 70                               |
| Review of Final Report<br>For Accuracy and<br>Clinical Content | 54                     | 59                               | 38                     | 71                               | 115                    | 64                               |
| Specimen Acceptability   | 54                     | 56                               | 38                     | 79                               | 114                    | 68                               |
| Evaluation of Frequency of Corrected Reports                   | 54                     | 56                               | 38                     | 47                               | 115                    | 25                               |
| Patient Satisfaction<br>Assessment                             | 54                     | 50                               | 38                     | 32                               | 115                    | 29                               |
| Ordering Accuracy  | 54                     | 48                               | 38                     | 50                               | 115                    | 50                               |
| Correlation Studies with<br>Other Labs                         | 54                     | 39                               | 38                     | 71                               | 115                    | 58                               |
| Physician Satisfaction<br>Assessment                           | 54                     | 26                               | 38                     | 29                               | 115                    | 29                               |
| Evaluation of<br>Frequency of Repeat<br>Analysis               | 54                     | 15                               | 38                     | 21                               | 115                    | 15                               |
| Evaluation of Patient<br>History vs Lab Result                 | 54                     | 13                               | 38                     | 29                               | 115                    | 32                               |
| Evaluation of Patient<br>Outcome vs Lab Result                 | 54                     | 6                                | 37                     | 19                               | 115                    | 25                               |

| Quality Assurance Monitor   | % of Labs that ranked as 4 or 5 | % of Labs that ranked as 3 | % of Labs that ranked as 2 or 1 |
|---|---------------------------------|----------------------------|---------------------------------|
|   | valuable<br>very valuable       |                            | little value<br>no value        |
| Quality Control Results   | 91                              | 6                          | 3                               |
| Proficiency Testing Results   | 88                              | 9                          | 3                               |
| Correlation Studies with Other Labs                                 | 79                              | 14                         | 7                               |
| Review of Final Patient Report for<br>Accuracy and Clinical Content | 76                              | 20                         | 4                               |
| Staff Meetings Where Lab Issues are Discussed                       | 76                              | 16                         | 8                               |
| Evaluation of Patient Outcome versus Lab<br>Results                 | 74                              | 18                         | 8                               |
| Evaluation of Patient History versus Lab<br>Results                 | 71                              | 23                         | 6                               |
| Incident Reports Related to Lab Error                               | 68                              | 25                         | 7                               |
| Evaluation of Frequency of Corrected<br>Reports                     | 68                              | 13                         | 19                              |
| Specimen Acceptability  | 67                              | 23                         | 10                              |
| Ordering Accuracy   | 65                              | 28                         | 7                               |
| Physician Satisfaction Assessment                                   | 65                              | 26                         | 9                               |
| Documentation of Personnel Competency                               | 57                              | 28                         | 15                              |
| Evaluation of Frequency of Repeat<br>Analysis                       | 55                              | 18                         | 27                              |
| Patient Satisfaction Assessment                                     | 47                              | 38                         | 15                              |

 TABLE 9
 Ranking of Value of Feedback of Quality Assurance Monitors - All Lab Types

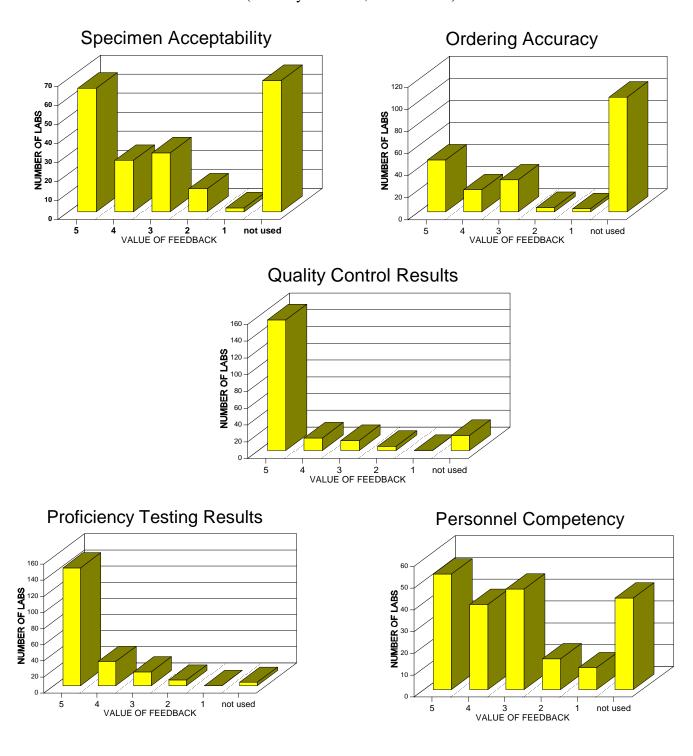
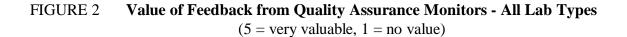
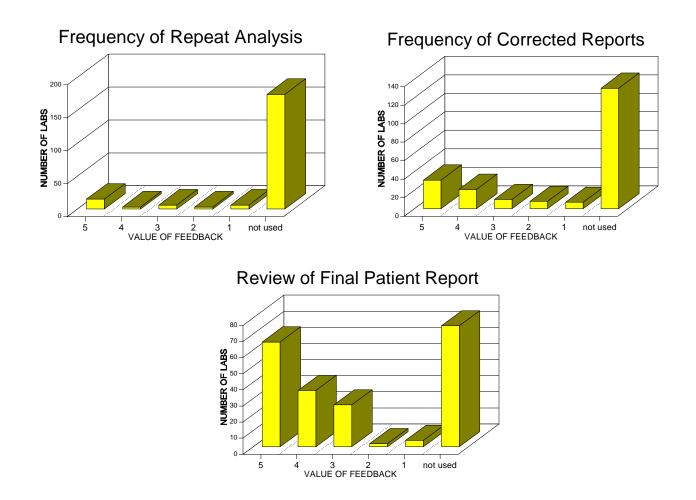


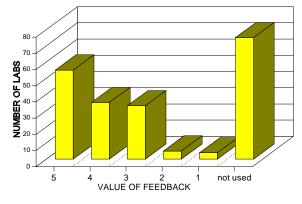
FIGURE 1 Value of Feedback from Quality Assurance Monitors - All Lab Types (5 = very valuable , 1 = no value)



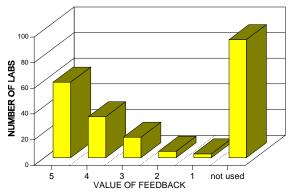


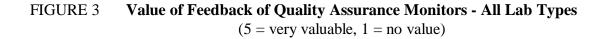


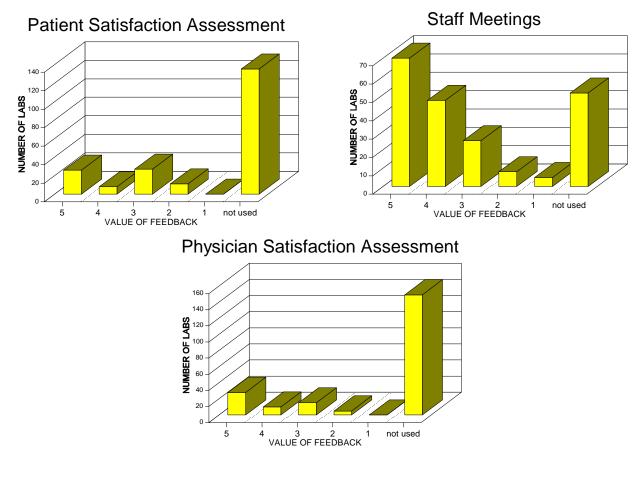
Incident Reports Related to Lab Error

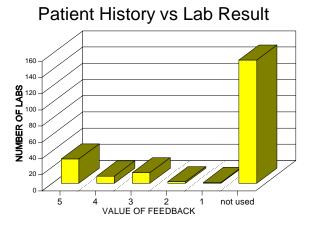


# Correlation Studies With Other Labs

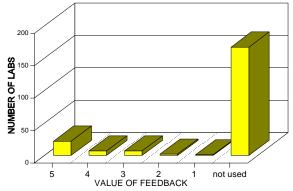








Patient Outcome vs Lab Result



| Арр                   | endix i                  |   |    |    |    |    |  |  |  |
|-----------------------|--------------------------|---|----|----|----|----|--|--|--|
|                       | Labs That<br>Use Monitor | Rank of Value of Feedback from Monitor<br>(1 = no value, 5 = very valuable) |    |    |    |    |  |  |  |
|                       | Ν                        | % of Labs*  |    |    |    |    |  |  |  |
|                       |                          | 1   | 2  | 3  | 4  | 5  |  |  |  |
| SPECIMEN ACCEPTABILIT | Y                        |   |    |    |    |    |  |  |  |
| All Labs              | 137                      | 1   | 9  | 23 | 20 | 47 |  |  |  |
| Hospital Labs         | 30                       | 0   | 10 | 27 | 20 | 43 |  |  |  |
| Independent Labs      | 30                       | 3   | 7  | 20 | 17 | 53 |  |  |  |
| Physician Office Labs | 77                       | 1   | 9  | 22 | 21 | 47 |  |  |  |
| ORDERING ACCURACY     |                          |   |    |    |    |    |  |  |  |
| All Labs              | 103                      | 3   | 4  | 28 | 19 | 46 |  |  |  |
| Hospital Labs         | 26                       | 4   | 0  | 31 | 27 | 38 |  |  |  |
| Independent Labs      | 19                       | 0   | 5  | 26 | 21 | 48 |  |  |  |
| Physician Office Labs | 58                       | 3   | 5  | 28 | 16 | 48 |  |  |  |
| QUALITY CONTROL RESU  | LTS                      |   |    |    |    |    |  |  |  |
| All Labs              | 188                      | 0   | 3  | 6  | 8  | 83 |  |  |  |
|                       |                          |   |    |    |    |    |  |  |  |

| Physician Office Labs  | 58               | 3  | 5  | 28 | 16 | 48 |
|------------------------|------------------|----|----|----|----|----|
| QUALITY CONTROL RESUL  | TS               |    |    | _  |    |    |
| All Labs               | 188              | 0  | 3  | 6  | 8  | 83 |
| Hospital Labs          | 51               | 0  | 0  | 6  | 12 | 82 |
| Independent Labs       | 35               | 0  | 3  | 9  | 6  | 82 |
| Physician Office Labs  | 102              | 0  | 4  | 6  | 7  | 83 |
| PROFICIENCY TESTING RE | SULTS            |    | -  |    |    | -  |
| All Labs               | 200              | 0  | 3  | 9  | 15 | 73 |
| Hospital Labs          | 53               | 0  | 2  | 6  | 24 | 68 |
| Independent Labs       | 37               | 0  | 3  | 13 | 8  | 76 |
| Physician Office Labs  | 110              | 0  | 4  | 8  | 13 | 75 |
| DOCUMENTATION OF PERS  | SONNEL COMPETENC | CY |    | -  | -  |    |
| All Labs               | 162              | 6  | 9  | 28 | 24 | 33 |
| Hospital Labs          | 41               | 7  | 10 | 32 | 29 | 22 |
| Independent Labs       | 32               | 0  | 6  | 34 | 25 | 34 |
| Physician Office Labs  | 89               | 8  | 9  | 25 | 21 | 37 |

\* Note: In some cases, the sum of the values may not equal 100% due to rounding

# Appendix ii

| Labs that<br>use monitor |             | Rank of Value of Feedback from Monitor<br>(1 = no value, 5 = very valuable) |   |   |   |  |  |  |
|--------------------------|-------------|---|---|---|---|--|--|--|
| Ν                        | % of Labs * |   |   |   |   |  |  |  |
|                          | 1           | 2   | 3 | 4 | 5 |  |  |  |

#### EVALUATION OF FREQUENCY OF REPEAT ANALYSIS

| EVALUATION OF FREQUENCY OF         | F REPEAT ANALYSIS |        |          |        |    |    |
|------------------------------------|-------------------|--------|----------|--------|----|----|
| All Labs                           | 33                | 18     | 9        | 18     | 9  | 46 |
| Hospital Labs                      | 8                 | 25     | 13       | 13     | 0  | 50 |
| Independent Labs                   | 8                 | 0      | 0        | 50     | 13 | 38 |
| Physician Office Labs              | 17                | 23     | 12       | 6      | 12 | 47 |
| EVALUATION OF FREQUENCY OI         | F CORRECTED REPOR | TS     |          |        |    |    |
| All Labs                           | 77                | 9      | 10       | 13     | 27 | 40 |
| Hospital Labs                      | 30                | 7      | 13       | 17     | 23 | 40 |
| Independent Labs                   | 18                | 0      | 11       | 11     | 33 | 44 |
| Physician Office Labs              | 29                | 17     | 7        | 10     | 28 | 38 |
| <b>REVIEW OF FINAL PATIENT REP</b> | ORT FOR ACCURACY  | AND CL | INICAL ( | CONTEN | T  | -  |
| All Labs                           | 132               | 3      | 1        | 20     | 27 | 49 |
| Hospital Labs                      | 32                | 6      | 6        | 22     | 22 | 44 |
| Independent Labs                   | 27                | 0      | 0        | 26     | 30 | 44 |
| Physician Office Labs              | 73                | 3      | 0        | 17     | 27 | 53 |
| INCIDENT REPORTS RELATED TO        | ) LAB ERROR       |        |          |        |    |    |
| All Labs                           | 132               | 3      | 4        | 25     | 26 | 42 |
| Hospital Labs                      | 42                | 0      | 7        | 24     | 26 | 43 |
| Independent Labs                   | 29                | 0      | 0        | 28     | 28 | 45 |
| Physician Office Labs              | 61                | 7      | 3        | 25     | 26 | 39 |
| CORRELATION STUDIES WITH O'        | THER LABS         |        |          |        |    |    |
| All Labs                           | 115               | 3      | 4        | 14     | 28 | 51 |
| Hospital Labs                      | 21                | 5      | 0        | 14     | 57 | 24 |
| Independent Labs                   | 27                | 4      | 0        | 11     | 26 | 59 |
|                                    |                   |        |          |        | 19 | 57 |

\*Note: In some cases, the sum of the values may not equal 100% due to rounding

| Labs That<br>Use Monitor | Rank of Value of Feedback from Monitor<br>(1 = no value, 5 = very valuable) |   |   |   |   |  |  |  |
|--------------------------|---|---|---|---|---|--|--|--|
| Ν                        | % of Labs *   |   |   |   |   |  |  |  |
|                          | 1   | 2 | 3 | 4 | 5 |  |  |  |

## STAFF MEETINGS WHERE LAB ISSUES ARE DISCUSSED

| STAFF MEETINGS WHERE LAD IS | SOLS ARE DISCUSSED | )    |    |    |    |     |
|-----------------------------|--------------------|------|----|----|----|-----|
| All Labs                    | 155                | 3    | 5  | 16 | 30 | 45  |
| Hospital Labs               | 41                 | 2    | 2  | 12 | 39 | 44  |
| Independent Labs            | 34                 | 0    | 6  | 27 | 29 | 38  |
| Physician Office Labs       | 80                 | 5    | 6  | 14 | 26 | 49  |
| PATIENT SATISFACTION ASSESS | MENT               | -    | -  | -  | -  |     |
| All Labs                    | 72                 | 0    | 15 | 38 | 11 | 36  |
| Hospital Labs               | 27                 | 0    | 22 | 26 | 11 | 41  |
| Independent Labs            | 12                 | 0    | 0  | 58 | 25 | 17  |
| Physician Office Labs       | 33                 | 0    | 15 | 39 | 6  | 39  |
| PHYSICIAN SATISFACTION ASSE | SSMENT             |      | -  |    | -  |     |
| All Labs                    | 58                 | 0    | 9  | 26 | 17 | 48  |
| Hospital Labs               | 14                 | 0    | 7  | 36 | 14 | 43  |
| Independent Labs            | 11                 | 0    | 0  | 18 | 27 | 55  |
| Physician Office Labs       | 33                 | 0    | 12 | 24 | 15 | 49  |
| EVALUATION OF PATIENT HISTO | ORY VERSUS LAB RES | ULT  |    | -  |    | -   |
| All Labs                    | 55                 | 2    | 4  | 23 | 16 | 55  |
| Hospital Labs               | 7                  | 0    | 14 | 0  | 0  | 86  |
| Independent Labs            | 11                 | 9    | 0  | 9  | 27 | 55  |
| Physician Office Labs       | 37                 | 0    | 3  | 32 | 16 | 49  |
| EVALUATION OF PATIENT OUTC  | OME VERSUS LAB RE  | SULT |    |    |    |     |
| All Labs                    | 39                 | 3    | 5  | 18 | 18 | 56  |
| Hospital Labs               | 3                  | 0    | 0  | 0  | 0  | 100 |
| Independent Labs            | 7                  | 14   | 0  | 14 | 29 | 43  |
| 1                           |                    |      |    |    |    |     |

\* Note: In some cases, the sum of the values may not equal 100% due to rounding